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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,016	08/30/2001	Carlos Martinez Alonso	46309-253995	8132

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EXAMINER	
YAEN, CHRISTOPHER H	
ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/787,016	ALONSO ET AL.	
	Examiner	Art Unit	
	Christopher H. Yaen	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-40,58 and 61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-40,58 and 61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

RE: ALONSO *et al*

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/17/2006 has been entered.

2. Claims 1-36, 41-57, and 59-60 are canceled without prejudice or disclaimer.

3. Claims 37-40,58, and 61 are pending and examined on the merits.

Specification

4. The disclosure is objected to because of the following informalities:

a. The specification and the drawings of the instant application contain sequences that have not been associated with a specific sequence identifier or SEQ ID No (see figures/drawings and brief description of drawings). 37 CFR 1.82(d) requires the use of the assigned sequence identifier (SEQ ID No:) in all instances where the description of a patent applicaton refers to a sequence and whenever a sequence or fragment thereof is claimed (see MPEP 2422.03). Applicant is also asked to review the specification of the instant application for any other non-compliant issues pertaining to biological data information. **Failure**

to supply the appropriate sequence identification numbers in response to this action will be considered non-responsive.

Appropriate correction is required.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

5. The rejection of claims 37-40,58, and 61 under 35 USC § 112, 1st paragraph as lacking written description is maintained for the reasons of record. Applicant argues that the terms "variants" and "alleles" means they are derived from the sequence provided in the application and have the same function. Applicant further contends that that the structure of the DOI-1 polypeptide is described in the specification and in the drawings and that sufficient disclosure in the specification would lead one of skill in the art to conclude that the applicant was in possession of the genus of variants claimed and would readily identify sequences that are able to maintain function. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The written description guidelines, example 11, provide guidance for allelic variants. The specification does not provide a definition of alleles, therefore the conventional or ordinary meaning of the term may be used (i.e. one of two or more alternate forms of a gene occupying the same locus in a particular chromosome or linkage structure and differing from other alleles of the locus at one or more mutational sites. See, Rieger et al.,*Glossary of Genetics* (1991), p. 16.). one of two or more alternate forms of a gene occupying the same locus in a particular chromosome or

linkage structure and differing from other alleles of the locus at one or more mutational sites. See, Rieger et al., *Glossary of Genetics* (1991), p. 16. The Rieger reference discloses that there are at least seven different kinds of allele.(see, Rieger, pp. 16-17 (amorphs, hypomorphs, hypermorphs, antimorphs, neomorphs, isoalleles, and unstable alleles)) The specification discloses only limited number of alleles within the scope of the genus of allelic variants (i.e. SEQ ID No: 1 and 2). The specification indicates that members of the genus are those that are defined as being derived from the sequences provided in the specification (see page 2). There is no description of the mutational sites that exist in nature, and there is no description of how the structure of SEQ ID NO: 1 or 2 relates to the structure of the genus of alleles as defined by the ordinary meaning of the term. The general knowledge in the art concerning alleles does not provide any indication of how the structure of one allele is representative of unknown alleles. The nature of alleles is that they are variant structures, and in the present state of the art the structure of one does not provide guidance to the structure of others. The common attributes of the genus are not described. One of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only one member of this genus is not representative of the variants of the genus and is insufficient to support the claim.

The written description guidelines, example 13, provides guidance for protein variants. In particular, claim 2 of the example indicates a protein variant of a specifically disclosed sequence. As in the instant case, the specification of the example provides little guidance aside from general knowledge provided in the art in terms of what types

of variations or deviations form the provided sequence can be made to the sequence. No common attributes or structural attributes have been provided in the specification or claims. Moreover, the instant claims do not provide sufficient structural and functional characteristics coupled with a known or disclosed correlation between function and structure. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus of "functional variants of the DIO-1 polypeptide".

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species; then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3).

Therefore, the rejection of claims under 35 USC 112, 1st paragraph is maintained for the reasons of record.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

6. The rejection of claims 58 and 61 under 35 USC § 112, 1st paragraph is maintained for the reasons of record. Applicant argues that the in vitro experiments

provided in the specification are indicative of in vivo situations. Specifically, applicant argues that there is no reason to doubt that administration of the peptide in vitro would be any different in vivo. Applicant further support his assertions by indicating that the studying of apoptotic pathways are "exclusively" performed in vitro, and that "the *in vitro* data presented are thus representative of the *in vitro* situation". Applicant further contends that the use of the peptide has been confirmed and found effective in vivo experiments. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Arguments of counsel may be effective in establishing that an examiner has not properly met his or her burden or has otherwise erred in his or her position. In these situations, an examiner may have failed to set forth any basis for questioning the adequacy of the disclosure or may not have considered the whole specification, including the drawings and the written description. However, it must be emphasized that arguments of counsel alone cannot take the place of evidence in the record once an examiner has advanced a reasonable basis for questioning the disclosure. See In re Budnick, 537 F.2d at 538, 190 USPQ at 424; In re Schulze, 346 F.2d 600, 145 USPQ 716 (CCPA 1965); In re Cole, 326 F.2d 769, 140 USPQ 230 (CCPA 1964). In the instant case, applicant's assertions that experiments performed in vitro are indicative of in vivo are not supported by any objective facts or provided in the form of an affidavit. Moreover, there is art of record (see action mailed on 6/30/2004) which substantiates that in vitro experimentation is not directly correlative to in vivo success. Applicant's

have not provided any arguments or objective evidence to overcome the showing of unpredictability.

With regard to examples demonstrated in figures 4 and 5 of the application, these are not commnensurate in scope, because the experiments are performed by over expressing a nucleic acid in an animal model and are not a pharmaceutical composition comprising a peptide.

Therefore, the rejection of claims under 35 USC 112, 1st paragraph as lacking an enabling disclosure is maintained for the reasons of record.

Claim Rejections Maintained - 35 USC § 102

7. The rejection of claims 37-39, and 61 under 35 USC § 102(b) as being anticipated by Nagase *et al* is maintained for the reasons of record. Applicant argues that the sequence as disclosed by Nagase *et al* is a partial sequence of the DIO-1 polypeptide and that components essential to the function of the DIO-1 polypeptide were not disclosed. Applicant further contends that "no function" to the sequence was assigned when the sequence was retrieved. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The term "functional variant" as recited in the claim has not been associated with any particular meaning in the specification as filed. Thus, the ordinary or conventional meaning of the term would encompass any protein having any function. Regardless of whatever function DIO-1 protein is currently claimed as possessing, the term functional variant encompasses any protein with an associated function. Contrary to applicant's

assertions, Nagase *et al* does in fact characterize the protein as having a possible function (see page 143 - one of eight possible functional characteristics). Thus, in the absence of the clear definition of the term functional variant, and given that the protein disclosed by Nagase *et al* is in fact "functional" and is derived and has considerable homology to the instantly claimed polypeptide, the sequence as taught by Nagase *et al* anticipates the instant claims as being a "variant".

Therefore, the rejection of claims under 35 USC 102(b) as being anticipated is maintained for the reasons of record.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen, Examiner
Art Unit 1643
February 6, 2006

CHRISTOPHER YAEN
PATENT EXAMINER